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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/349,489	12/02/1994	DAVID B. RING	0999.001	6479

7590 11/28/2005

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EXAMINER

TUNGATURTHI, PARITHOSH K

ART UNIT PAPER NUMBER

1643

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/349,489	Applicant(s) RING, DAVID B.	
	Examiner Parithosh K. Tungaturthi	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09.09.2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments filed on 09/09/2005 in response to the office action is acknowledged.
2. The text of those sections of Title 35 U.D.C. not included in this action can be found in prior office action.
3. Claims 1-3 and 8 are pending and examined on the merits.

Claim Rejections withdrawn:

4. The rejections of claims 1-3 and 8 under 35 U.S.C. 102(e) as being anticipated by Ring (U.S. Patent 5,959,084) as evidenced by Clark (Cancer Immunol. Immunothera. 44(5):265-272, 1997) and by Weiner (Cancer Research 55:4586-4593, 1995) are withdrawn in view of the amendments to the claims.

New Grounds of Rejection:

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for reciting "derived" in claims 1 and 2 for the exact meaning of the term is not clear. It is not clear if the term indicates a method step, a thought process or a design process. Additionally, it is not clear if the term includes any additional limitations for the "antigen binding site from the monoclonal antibody". As written, it is impossible for one skilled in the art to determine the metes

and bounds of the claims. The applicant can overcome the rejection by simply eliminating the term "derived" from the claim language.

6. It has been noted that the applicant did not provide the information pertaining to the deposit of the claimed hybridoma 3G8.

Claim 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the claimed hybridoma 3G8. It is not clear that the hybridoma 3G8 is known and publicly available or can be reproducibly isolated from nature without undue experimentation. It is noted that in paragraph 0045, the applicant discloses that "The term "3G8" as used herein refers to a monoclonal antibody produced by a hybridoma 3G8, which recognizes and binds to Fc.gamma.RIII which binds the Fc fragment of aggregated IgG, and was initially disclosed in Unkeless et al, J. Exp. Med. (1979) 150:580-596". However, the deposit requirement for the purposes of the prosecution of this application has not been satisfied.

Exact replication of an antibody is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed antibodies, this method will not necessarily reproduce antibodies which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive an

antibody identical to those claimed. Undue experimentation would be required to screen all of the possible antibody species to obtain the claimed antibodies.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed hybridoma 3G8, a suitable deposit is required for patent purposes, evidence of public availability or evidence of the reproducibility without undue experimentation of the claimed hybridoma 3G8, is required.

Applicant's failure to refer to the deposit information pertaining to the claimed hybridomas in the specification is noted and it is required that the required deposit be made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposit of the claimed hybridoma is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit of the claimed hybridoma has been accepted by an International Depository Authority under the provisions of the Budapest Treaty **and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application.** This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit of the claimed hybridoma 3G8 is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set

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forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to

corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.


Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Conclusion

16. Claim 8 is in condition for allowance.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER